

### **REMARKS / ARGUMENTS**

Applicant has carefully studied the outstanding Office Action. The present Amendment is intended to be fully responsive to all points of rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application are respectfully requested.

#### **Status of the Claims**

Claims 16-22 and 48-53 were withdrawn, without prejudice, in the Election and Amendment filed February 19, 2003. Claim 23 has been canceled, without prejudice. Claims 1-15 and 24-47 are pending. Claims 1-9, 13, 24-37, 41, 45 and 47 have been amended. Applicants respectfully assert that the amendments to claims 1-9, 13, 24-37, 41, 45 and 47 add no new matter.

#### **Interview Summary**

Applicants would like to thank the Examiner for the courtesy of the telephone interview with the Applicants' representative, Caleb Pollack, on July 29, 2003.

In the telephone interview a new proposed claim was discussed, in view of Schentag et al., United States Patent Number 5,279,607, Lemelson, United States Patent Number 5,993,378, and Iddan et al, United States Patent Number 5,604,531. Applicants' representative proposed the following proposed sample claim:

X. A method comprising:

inserting an in-vivo device into the gastrointestinal tract, the in-vivo device including at least a sensor and a transmitter;

receiving sensing signals corresponding to data received by the sensor;

generating a map from at least the sensing signals;  
inserting a second in-vivo device into the gastrointestinal tract; and  
determining the location of the second in-vivo device relative to the map.

While Applicants' representatives felt that the sample claim presented above was patentable over the prior art of record, the Examiner did not. Applicants' representative disagreed with the Examiner's position. In addition, Applicants' representative expressed Applicant's opinions regarding the differences between the map of Schentag and Applicants' limitations regarding creating a map from sensing signals (as opposed to mere beacon or location signals, as discussed by Schentag). The Examiner explained her reasons for the objections to the proposed claims, and Applicants' representative agreed to propose new amendments to the claims. Thus, Applicants' representative and the Examiner did not reach agreement during the interview; however, the positions of the Applicants and the Examiner were clarified.

#### **Objection to the Drawings:**

The Examiner objected to the drawings because the boxed elements of Fig. 6 were not labeled. As discussed above, Applicants have amended the drawings. Therefore, Applicants request that the objections to the drawings be withdrawn.

#### **Claim Objections**

The Examiner objected to claims 2 and 26-33 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicants have amended claims 1 and 2 to clarify what the Applicants regard as their invention. It is respectfully submitted that amended claim 2 meets the requirements

of 37 CFR 1.75(c), and therefore the objection to claim 2 under 37 CFR 1.75(c) should be withdrawn.

Applicants have amended claims 26-33 to clarify what the Applicants regard as their invention. It is respectfully submitted that amended claims 26-33 meet the requirements of 37 CFR 1.75(c), and therefore the objection to claims 26-33 under 37 CFR 1.75(c) should be withdrawn.

The Examiner objected to claims 37-47 because of informalities, and suggested replacement of terms to avoid confusion.

Applicants have amended claims 37 and 41, to clarify what the Applicants regard as their invention. It is respectfully submitted that the objection to claims 37-47 because of informalities should be withdrawn.

### **35 USC 112 Rejections**

The Examiner rejected claims 1-8, 23, 31-33 and 36-47 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Applicants have amended claims 1-8, 31-33, 35-37 and 41 to clarify what the Applicants regard as their invention. Applicants have canceled claim 23, without prejudice.

In light of the above mentioned amendments to the claims, it is respectfully submitted that rejected claims 1-8, 23, 31-33 and 36-47 meet the requirements of 35 USC 112, second paragraph, and therefore the rejection of claims 1-8, 23, 31-33 and 36-47 under 35 USC 112, second paragraph, should be withdrawn.

### 35 USC 101 Rejections

The Examiner rejected claim 23 under 35 USC 101 as a claimed recitation of a use without setting forth any steps involved in the process, resulting in a claim which is not a proper process claim under 35 USC 101.

Applicants have canceled claim 23, without prejudice. Therefore Applicants respectfully request that the rejection of claim 23 under 35 USC 101 should be withdrawn

The Examiner rejected claims 37-47 under 35 USC 101 as claims directed to non-statutory subject matter. Specifically, the Examiner contended that "the use of the term 'in-vivo device' implies that a living organism device is used which constitutes non-statutory subject matter."

It is submitted that the common use of the term "in-vivo device" refers generally to a non-living device (e.g., a mechanical device, an inanimate object) that is used inside a living organism. It is respectfully submitted that the use of the term "in-vivo device" does not mean that a living organism device is used, but rather means a device which may be used in-vivo is used. What is claimed is the method of use of the non-living device, not the use of an in-vivo environment or a living organism or structure. The word "device" implies and generally relates to a non-living organism. The ordinary meaning of the word "device", as well as many dictionary explanations of the word "device", refer to, for example, a machine, a tool or an instrument.

Furthermore, the term "in-vivo device", which is sometimes referred to in the Specification as a "sensing and utility device", clearly does not imply a living organism in the context of the Specification, but rather refers to a machine-like, non-living tool or instrument. For example, according to page 5, lines 23-24 in the Specification, "The

sensing and utility device may comprise, for example, any one or any combination of a video camera . . .". Other portions of the specification depict the device as a non-living entity, for example, page 8, lines 12-23.

It is noted that the adjective "in-vivo", by itself or in conjunction with the word "device", does not imply that the "device" is a living organism. The term "in-vivo" means "in the living body of a plant or animal" (Merriam Webster Collegiate Dictionary), such that an "in-vivo device" is a device (e.g., a non-living machine, instrument, or tool) which may be present inside a living organism.

For at least the reasons discussed above, it is respectfully submitted that claims 37-47 meet the requirements of 35 USC 101, and therefore the rejection of claims 37-47 under 35 USC 101 should be withdrawn.

### **35 USC 102 Rejections**

The Examiner has rejected claims 1-4, 6-9, 12, 23-28, 30-39, 41-43, and 45-47 under 35 USC 102(b) as being anticipated by Schentag et al., United States Patent Number 5,279,607 ("Schentag"). Applicants respectfully traverse the rejection of claims 1-4, 6-9, 12, 23-28, 30-39, 41-43, and 45-47 under 35 USC 102(b) as being anticipated by Schentag.

Amended claim 1 recites "inserting a first in-vivo device into a gastrointestinal tract, the first in-vivo device including at least a sensing device to sense selected parameters of the gastrointestinal tract". Schentag et al does not teach, disclose or suggest at least the element of a sensing device to sense selected parameters of the gastrointestinal tract. Schentag discloses an in-vivo device with a transmitter, the transmitter transmitting only a beacon or homing signals. Schentag does not include a sensing device to sense parameters of a body lumen, as does Applicants' claim 1, as amended. Such sensing of parameters is well supported by Applicants' Specification. For example, non-limiting

examples of the parameters sensed according to claim 1 may be images, temperature, pressure, pH, etc. Specification, p. 5 line 23 to p. 6, line 3.

In the July 29, 2003 interview, the Examiner had expressed concern that the claims, as presented during that interview, may read on a sensor to receive external (from the body) location signals. Applicants disagree with this position, and Applicants also assert that the element of the sensing device to sense "selected parameters of the gastrointestinal tract" claim 1 as currently amended, does not include and is not equivalent to a sensor to receive external location signals.

Applicants' claim 1, as amended, also includes the limitations of "receiving sensing signals ... corresponding to selected parameters of the gastrointestinal tract; [and] generating a map from at least the sensing signals." While, as Applicants' representative asserted in the July 29 interview, Schentag teaches creating a map (e.g., Schentag, col. 3, ll. 35-40), this map is based solely on directional or beacon signals received from the in-vivo device. In contrast, Applicants' claim 1, as amended, requires creating a map from sensing signals, the sensing signals corresponding to selected gastrointestinal tract parameters (e.g., images, pH, etc.). Schentag does not teach such limitations.

In order to successfully assert a prima facie case of anticipation, the Examiner must provide a single prior art document that includes every element and limitation of the claim or claims being rejected. Schentag lacks at least the elements of Applicants' claim 1, as amended, discussed above. Therefore Schentag does not anticipate Applicants' claim 1, as amended.

Similar to the limitations of Applicants claim 1 discussed above, Applicants' amended claim 9 recites "sensing means for sensing selected parameters of the gastrointestinal tract ... [and] means for generating a map from at least the selected parameters". Amended claim 24 recites "during a first pass, passing a first device through

a lumen and generating a map of the lumen from data related to selected parameters of the lumen sensed from the lumen and received from the first device". Amended claim 37 recites "comparing ... data to a map of an in-vivo lumen, the map generated from parameters sensed from the in-vivo lumen". Amended claim 41 recites "[a] map generated from parameters sensed from an in-vivo lumen". For at least the reasons discussed above with respect to claim 1, none of claims 9, 24, 37 or 41 are anticipated by Schentag.

It is respectfully submitted that independent claims 1, 9, 24, 37 and 41, as amended, are not anticipated by Schentag, because each of claims 1, 9, 24, 37 and 41 recites limitations not taught or suggested by Schentag.

Dependent claims 2-8, 10-12, 25-36, 38-40 and 42-47 are each dependent from one of independent claims 1, 9, 24, 37 and 41, and therefore each include all the limitations of one of these claims. Therefore, each of dependent claims 2-8, 10-12, 25-36, 38-40 and 42-47 is also allowable.

In view of the above amendment, and since claim 23 has been cancelled, it is respectfully submitted that the rejection of claims 1-4, 6-9, 12, 23-28, 30-39, 41-43, and 45-47 under 35 USC 102(b) should be withdrawn.

### **35 USC 103 Rejections**

The Examiner has rejected claims 10-11 under 35 USC 103(a) as being unpatentable over Schentag al in view of Lemelson, United States Patent Number 5,993,378 ("Lemelson").

Dependent claims 10-11 are dependent from amended independent claim 9, which, as discussed above, is allowable. Lemelson does not cure the deficiencies of Schentag. For example, Lemelson does not disclose generating a map from selected parameters of the

gastrointestinal tract. Therefore, it is respectfully submitted that dependent claims 10-11 are likewise allowable.

Therefore, Applicants respectfully request that the Examiner withdraw the rejection of claims 10-11 under 35 USC 103(a) as being unpatentable over Schentag et al in view of Lemelson.

The Examiner has rejected claims 4-5, 29, 40 and 44 under 35 USC 103(a) as being unpatentable over Schentag et al in view of Iddan et al, United States Patent Number 5,604,531 ("Iddan").

Claims 4-5, 29, 40 and 44 are each dependent from one of amended independent claims 1, 24, 37 and 41, respectively, which, as discussed above, are allowable. Iddan does not cure the deficiencies of Schentag. For example, Iddan does not disclose generating or using a map generated from signals or data corresponding to selected parameters of a body lumen or from portions of a lumen. Therefore, it is respectfully submitted that dependent claims 4-5, 29, 40 and 44 are also allowable. Applicants request that the Examiner withdraw the rejection of claims 4-5, 29, 40 and 44 under 35 USC 103(a) as being unpatentable over Schentag et al in view of Iddan.

The Examiner has rejected claims 13-15 under 35 USC 103(a) as being obvious over Iddan et al in view of Lemelson.

Amended claim 13 recites, inter alia, a system to "generate ... a map from video data" As discussed above, neither Iddan nor Lemelson, alone or in combination, teach or suggest such a limitation.

An obviousness rejection requires a teaching or a suggestion by the relied upon prior art of all the elements of a claim (M.P.E.P. §2142). Since neither Iddan nor



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Lemelson, alone or in combination, teach all the elements of Applicants' independent claim 13, as amended, neither Iddan nor Lemelson, alone or in combination, renders claim 13 obvious.

Dependent claims 14-15 are dependent from amended independent claim 13, and therefore include all the limitations of claim 13.

Applicants thus request that the Examiner withdraw the rejection of claims 13-15 under 35 USC 103(a) as being obvious over Iddan et al in view of Lemelson.

### Conclusion

In view of the foregoing amendment and remarks, claims 1-15 and 24-47 are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

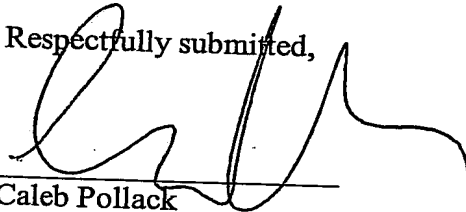
Should the Examiner have any question or comment as to the form, content or entry of this paper, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

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No fees are believed to be due. However, if any fees are due, please charge any such fees to deposit account No. 05-0649.

Respectfully submitted,



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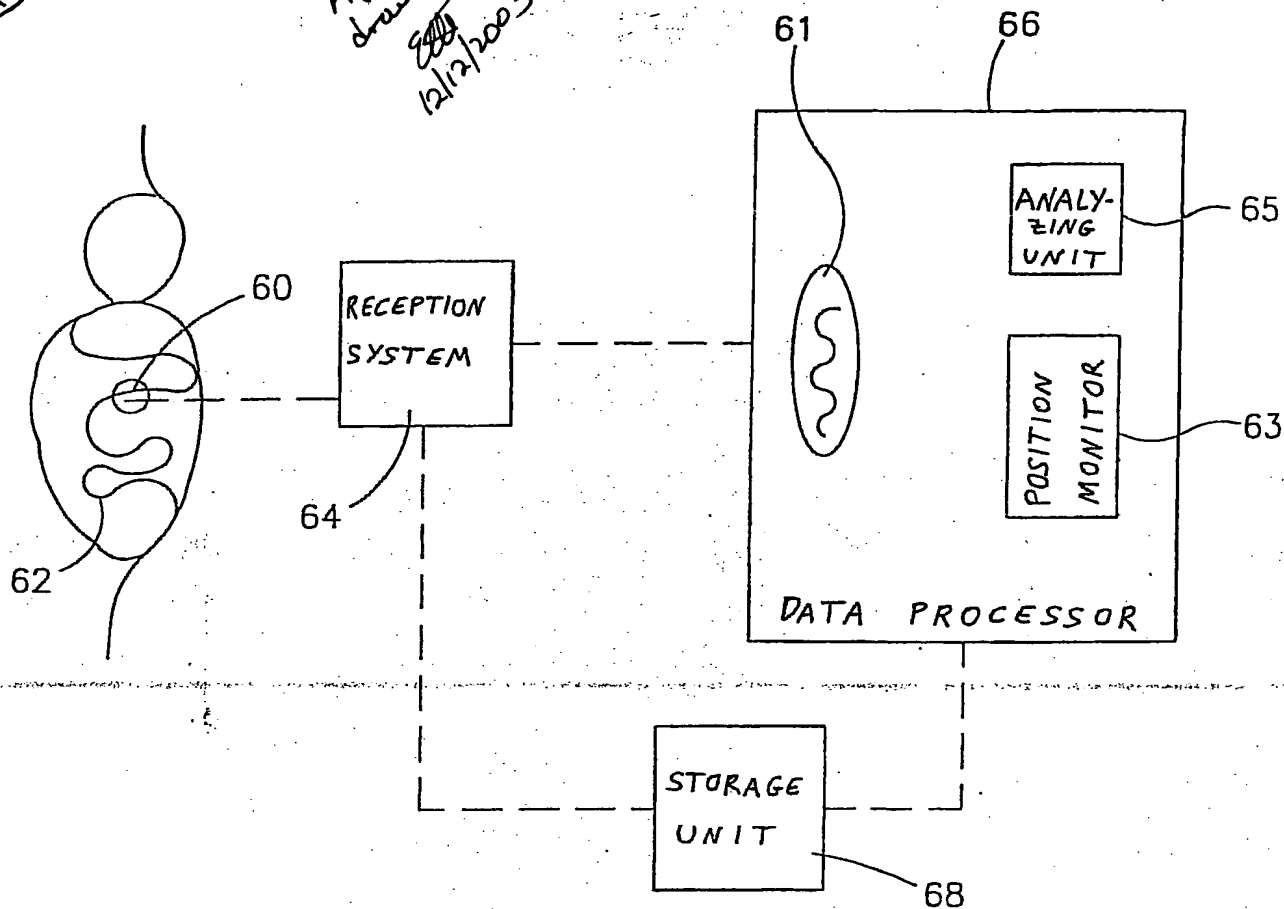


FIG. 6

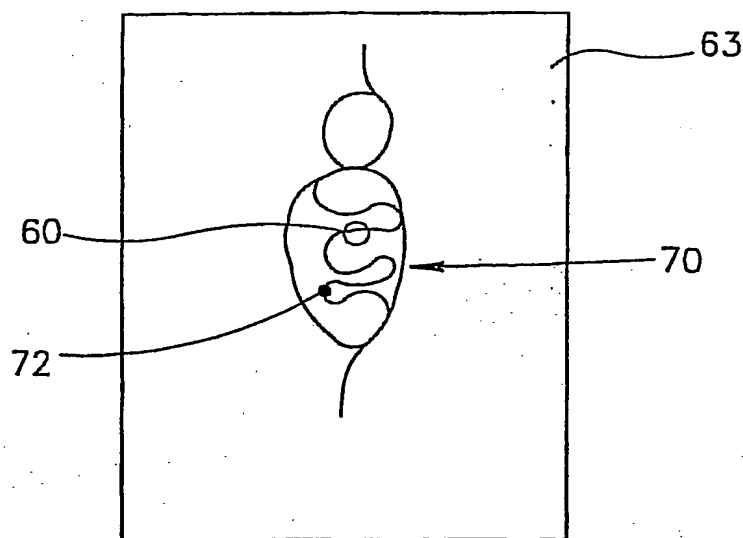


FIG. 7